## REMARKS

Claims 1-42 are pending in the present application. Claims 1-38 have been currently amended. New Claims 39-42 have been added. Support for the amended and new claims can be found throughout the specification and in the original claims.

Applicants respectfully submit that Applicants' claimed invention is support by the priority applications listed in Applicants' claim of priority under 35 U.S.C. §120. Applicants submit that U.S. Application No. 08/138,271 and the applications that derive from this application provide sufficient disclosure of various nucleic acids. The 08/138,271 application (page 17), in addition to the present application (pages 21 and 23), also cites "Schmolka I.R., *J. Am. Oil Chemist Soc.*, 54:110-116 (1977)," which describes octablock copolymers. This reference is attached as "Exhibit A." In addition, Applicants submit that U.S. Application Serial No. 08/889,342, now U.S. Patent 5,990,241, describes octablock copolymers (see column 10, line 66 – column 11, line 39 and column 12, lines 28-33). U.S. Patent 5,990,241 also incorporates by reference U.S. Application Serial No. 07/107,358, now U.S. Patent 5,114,708, and U.S. Application Serial No. 07/610,417, now U.S. Patent 5,183,678, which both provide sufficient disclosure of octablock copolymers. Therefore, Applicants respectfully submit that Applicants' claimed compositions, comprising the combination of an octablock copolymer and a nucleic acid, are supported by the combination of patents listed under Applicants' claim of priority, and that Applicants' pending claims should have a priority date of at least October 15, 1993.

Applicants respectfully request reconsideration of the present claims in view of the foregoing amendments and following remarks.

### Compliance with Sequence Listing Rules

Applicants respectfully submit that a Sequence Listing for the nucleotide sequence provided on page 31, line 30 of the specification is enclosed with this response in accordance with 37 C.F.R. 1.821-1.825.

**Rejection of Claims 1-38 under 35 U.S.C. §112, First Paragraph (Enablement)**

The Examiner rejected Claims 1-38 under 35 U.S.C. §112, first paragraph, as lacking enablement. Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully submit that the law does not necessarily limit the claim scope only to those embodiments actually disclosed in the specification. In principle, one can support broad claims without a single disclosed embodiment. See *Spectra-Physics Inc. v. Coherent Inc., 827 F.2d 1524, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987).* Moreover, the specification may contain a written description of a broadly claimed invention without describing all species encompassed by the claim. See *Utter v. Hiraga, 845 F.2d 993, 998, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988).* Also, an embodiment need not necessarily been reduced to practice. See *In re Wright, 999 F.2d 1557, 1561, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993) ("Nothing more than objective enablement is required, and therefore it is irrelevant whether a teaching is provided through broad terminology or illustrated examples.")* Also, "the absence of a working example does not in and of itself compel the conclusion that a specification does not satisfy the requirements of 112." *In re Long, 368 F.2d 892, 895, 151 U.S.P.Q. 640, 642 (C.C.P.A. 1966).*

Applicants' specification discloses compositions comprising the recited octablock copolymers and a compound capable of altering nucleic acid function. Such disclosures are found on the following pages, including, but not limited to, page 7, line 16 – page 9, line 8; page 9, lines 9-15, and pages 23-28. The specification also provides that any of the surface active block copolymers can be combined with a variety of molecules capable of altering nucleic acid function (see page 31, lines 5-8). Compound capable of altering nucleic acid function, including various genes and oligonucleotides, are disclosed on the following pages, including, but not limited to, pages 1-6 and 31-37. The specification also incorporates U.S. Patent 5,494,660, by reference, on page 28, which provides for the preparation oil-in-water emulsions of the octablock copolymers (see column 26, lines 9 – 61). These emulsions can be used in the preparation of the compositions of the present invention. See also the present specification, page 18, lines 13-15, which provides that the compositions of the present invention include, but are not limited to, aqueous solutions, suspensions or emulsions, such as oil-in-water emulsions. The specification also provides that an effective amount of an

antisense compound will result in a blood concentration of 1 μM to 100 μM, and that 6 mM to 600 mM of an oligonucleotides concentration is required when 1 ml injections are administered to an average person containing 6.25 liters of blood (see page 32, lines 2-15). Descriptive text of Applicants' claimed compositions can also be found throughout the specification, including, but not limited to, pages 6-9, 12-15 and 28-29.

Applicants' specification also discloses that the compositions of the present invention can be administered by a number of routes including, but not limited to, topical, transdermal, oral, trans-mucosal, subcutaneous injection, intravenous injection, interperitoneal injection and intramuscular injection (see page 9, lines 16-20). Descriptive text of Applicants' claimed methods of delivery can also be found throughout the specification, including, but not limited to, pages 6-9, 12-15 and 28-29.

Therefore, for at least the above reasons, Applicants respectfully submit that Claims 1-38 are enabled by Applicant's specification. Accordingly, Applicants request the withdrawal of the above 112 rejection.

**Rejection of Claims 1-38 under 35 U.S.C. §112, First Paragraph (Written Description)**

The Examiner rejected Claims 1-38 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection for the following reasons.

An adequate written description of the claimed invention may be shown by any description of sufficient, relevant, identifying characteristics, so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. MPEP 2163. Moreover, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species ..., or by disclosure of relevant identifying characteristics ..., by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP 2163. Applicants' specification provides sufficient description of the terms "genes,"

"oligonucleotides," "antisense oligonucleotides," "triplex DNA compounds" and "ribozymes," by using identifying characteristics, functional characteristics and/or descriptive representations. For example, the term "genes" is defined by relevant characteristics and functional characteristics on the following pages of the specification: page 4, lines 2-3 (genes that code for therapeutic compounds); page 16, lines 5-6 (genes that code for the gene product to be immunized against); and page 16, lines 12-14 (genes that code for compounds effective for killing, reducing or retarding cancer). "Oligonucleotides" are defined in term of relevant characteristics and functional characteristics on the following pages of the specification: page 2, lines 24-25 (oligonucleotides that are complimentary to certain gene messages or viral sequences); and page 4, lines 24-25 (oligonucleotides that specifically bind to particular regions of duplex DNA, thereby inactivating the target gene). "Antisense oligonucleotides" are defined in term of relevant characteristics and functional characteristics on the following pages of the specification: page 2, lines 23-25 (oligonucleotides that are complimentary to certain gene messages or viral sequences); and page 30, lines 3-5 (antisense oligonucleotides use for altering or regulating gene expression and/or protein translation). "Triplex DNA compounds" are defined in term of relevant characteristics and functional characteristics on the following page of the specification: page 4, lines 23-26 (triplex DNA compounds specifically bind to particular regions of duplex DNA to inactivate the target gene). "Ribozymes" are defined in term of relevant characteristics and functional characteristics on page 5, lines 3-8 of the specification (ribozymes are catalytic RNA molecules that consist of a hybridizing region and an enzymatic region).

Applicants also submit that representative examples of "genes" are found on pages 32-34 of the specification (adenosine deaminase gene, gD gene of *Herpes simplex* virus type-1). Representative examples of antisense oligonucleotides are found on page 31, lines 22-26 and lines 27-31 of the specification (antisense oligonucleotides sequence, such as those disclosed by Matsukara et al. are incorporate by reference; a sequence complimentary to regions of the *art/trs* genes of HIV are prepared according to the method of Matsukara).

For at least the above reasons, Applicants respectfully submit that Claims 1-38 are sufficiently described in the specification as to reasonable convey to one skilled in the art, that

the Applicants, at the time the present application was filed, had possession of the claimed invention. Accordingly, Applicants request the withdrawal of the above 112 rejection.

**Rejection of Claims 1-38 under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected Claims 1-38 under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention. The Examiner asserted that Claims 1-38 were indefinite because they recite "human" and "animal" in the alternative, and humans are animals. The Examiner also asserted that these claims lacked proper antecedent basis for the term "the compound." The Examiner found Claims 5, 13, 23 and 31 indefinite due to the term "genes." The Examiner also found Claims 7, 15, 25 and 37 indefinite due to the trademark/trade name "Tween 80." Finally, the Examiner found Claims 24, 25, 32 and 37 indefinite because it was unclear how these method claims were furthered by including a surfactant or an alcohol, and method Claims 26 and 38 indefinite due to the inclusion of an expression vector. Applicants respectfully traverse this rejection for the following reasons.

Applicants have amended Claims 19, 27 and 33 to recite "animal" in place of "human and animal," in accordance with the Examiner's suggestion. Applicants respectfully submit that the term "animal" now refers to both humans and animals. Applicants have amended Claims 1-4, 9-12, 17-22, 27-30 and 33-36 to replace the term "compound" in the expression "about 40% of the compound by weight" and related expressions, with the phrase "octablock copolymer," which provides a proper antecedent basis for these claims. Applicants have also amended Claims 7, 15, 25 and 37 to replace the trade name "Tween 80" with its chemical name polyoxyethylene (20) sorbitan monooleate. Applicants have amended Claims 24, 26, 32, and 38 to provide that the composition used in these method claims contain the additional respective components. Applicants have also amended Claims 1, 9, 17, 19, 27 and 33 to recite, "isolated or amplified nucleic acid sequences encoding gene products." Applicants respectfully submit that this phrase refers to both open reading frame sequences and those sequences adjacent to, or including, one or more noncoding sequences.

Therefore, for at least the above reasons, Applicants respectfully assert that Claims 1-38 are definite, and request the withdrawal of this rejection.

**Rejection of Claims 1-4, 9-12, 17-22, 27-30 and 33-36 under 35 U.S.C. §102(b)**

The Examiner rejected Claims 1-4, 9-12, 17-22, 27-30 and 33-36 under 35 U.S.C. §102(b), as anticipated by U.S. Patent 5,234,683 to Hunter et al. (hereinafter "Hunter"). Applicants respectfully traverse this rejection for the following reasons.

Hunter teaches biologically-active copolymers that when injected into an animal or human with an antigen causes immunosuppression to the antigen (abstract). Applicants pending claims are directed to compositions comprising octablock copolymers **and** one or more molecules selected from isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA compounds, ribozymes, or mixtures thereof; and related methods of delivering a molecule to an animal using these compositions. Applicants respectfully submit that Hunter fails to teach or suggest compositions comprising isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA compounds, or ribozymes, and therefore, does not teach or suggest Applicants' claimed compositions or methods.

For at least the above reasons, Applicants respectfully submit that Hunter does not anticipate Claims 1-4, 9-12, 17-22, 27-30 and 33-36, and respectfully request the withdrawal of this rejection.

**Rejection of Claims 1-4, 9-12, 17-22, 27-30 and 33-36 under 35 U.S.C. §102(b)**

The Examiner rejected Claims 1-4, 9-12, 17-22, 27-30 and 33-36 under 35 U.S.C. §102(b), as anticipated by U.S. Patent 4,902,500 to Jansen et al. (hereinafter "Jansen"). Applicants respectfully traverse this rejection for the following reasons.

Jansen teaches stable antibody preparations containing a mixture of at least one polyoxypropylene-polyoxyethylene block copolymer and at least one phospholipid (abstract). Applicants pending claims are directed to compositions comprising octablock copolymers and one or more molecules selected from isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA compounds, ribozymes, or mixtures thereof; and related methods of delivering a molecule to an animal using these compositions. Applicants respectfully submit that Jansen fails to teach or suggest

compositions comprising isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA compounds, or ribozymes, and therefore, does not teach or suggest Applicants' pending claims.

For at least the above reasons, Applicants respectfully submit that Jansen does not anticipate Claims 1-4, 9-12, 17-22, 27-30 and 33-36, and respectfully request the withdrawal of this rejection.

**Rejection of Claims 1-5, 8-13, 16-23, 26-31, 33-36 and 38 under 35 U.S.C. §102(e)**

The Examiner rejected Claims 1-5, 8-13, 16-23, 26-31, 33-36 and 38 under 35 U.S.C. §102(e), as anticipated by U.S. Patent 6,359,054 to Lemieux et al. (hereinafter "Lemieux"). Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully submit that Applicants' invention should have a priority date of at least October 15, 1993, and thus, Lemieux cannot be considered prior art. Applicants also note that Lemieux does not teach the limitations of at least the following Claims: 2-4, 12, 18, 20-22, 30 and 36. Applicants respectfully request the withdrawal of this rejection.

**Rejection of Claims 6, 7, 14, 15, 24, 25, 32 and 37 under 35 U.S.C. §103(a)**

The Examiner rejected Claims 6, 7, 14, 15, 24, 25, 32 and 37 under 35 U.S.C. §103(a), as obvious over U.S. Patent 5,234,683 ("Hunter"). Applicants respectfully traverse this rejection for the following reasons.

As discussed above, Applicants respectfully submit that Hunter fails to teach or suggest compositions comprising isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA compounds, or ribozymes, and therefore, does not teach or suggest Applicants' claimed compositions or methods.

For at least the above reasons, Applicants respectfully submit that Hunter does not teach or suggest Claims 6, 7, 14, 15, 24, 25, 32 and 37, and respectfully request the withdrawal of this rejection.

**Rejection of Claims 1, 2, 5, 8, 17-20, 23 and 26 under 35 U.S.C. §103(a)**

The Examiner rejected Claims 1, 2, 5, 8, 17-20, 23 and 26 under 35 U.S.C. §103(a), as obvious over Pahlson et al. (Acta Pathol. Microl. Immunol. Scand. B (1986) 94(3): 117-125), in view of Woodard (Laboratory Animal Science 1989 May 39(3): 222-225). Hereinafter "Pahlson" and "Woodard," respectively. Applicants respectfully traverse this rejection for the following reasons.

Pahlson teaches whole bacteria emulsified in Freund's adjuvant. Woodward teaches a series of cationic amine and diamine surfactants, nonionic surfactants, and traditional vaccine adjuvants used to induce serum IgG antibody. Applicants pending claims are directed to compositions comprising octablock copolymers and one or more molecules selected from isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA compounds, ribozymes, or mixtures thereof; and related method of delivering a molecule to an animal using these compositions. Applicants respectfully submit that Pahlson, in view of Woodard, fails to teach or suggest compositions comprising isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA compounds, or ribozymes, and therefore, do not teach or suggest Applicants' claimed compositions or methods.

For at least the above reasons, Applicants respectfully submit that these combined references does not teach or suggest Claims 1, 2, 5, 8, 17-20, 23 and 26, and respectfully request the withdrawal of this rejection.

**Rejection of Claims 3, 4, 9-13, 16, 21, 22, 27-31, 33, 35, 36 and 38 under 35 U.S.C. §103(a)**

The Examiner rejected Claims 3, 4, 9-13, 16, 21, 22, 27-31, 33, 35, 36 and 38 under 35 U.S.C. §103(a), as obvious over Pahlson and Woodard, in further view of Jansen (U.S. Patent 4,902,500). Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully submit that Pahlson and Woodard, in further view of Jansen, fail to teach or suggest compositions comprising isolated or amplified nucleic acid sequences encoding gene products, oligonucleotides, antisense oligonucleotides, triplex DNA

compounds, or ribozymes, and therefore, do not teach or suggest Applicants' claimed compositions and methods.

For at least the above reasons, Applicants respectfully submit that these combined references do not teach or suggest Claims 3, 4, 9-13, 16, 21, 22, 27-31, 33, 35, 36 and 38, and respectfully request the withdrawal of this rejection.

**Rejection of Claims 1-5, 8-13, 16-18, 20-22, 28-30 and 34-36 under 35 U.S.C. §103(a)**

The Examiner rejected Claims 1-5, 8-13, 16-18, 20-22, 28-30 and 34-36 under 35 U.S.C. §103(a), as obvious over U.S. Patent 5,656,611 to Kabanov et al. (hereinafter "Kabanov"). Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully submit that Applicants' invention should have a priority date of at least October 15, 1993, and thus, Kabanov cannot be considered prior art. Applicants also note that Kabanov does not teach the claim limitations of Applicants' pending claims. Applicants respectfully request the withdrawal of this rejection.

## CONCLUSION

Claims 1-42 are pending in the present application. Claims 1-38 have been amended. New Claims 39-42 have been added. For at least the reasons given above, Applicants respectfully submit that the pending claims define patentable subject matter. Accordingly, Applicants respectfully request allowance of these claims.

A check in the amount of $465.00, the fee for a three-month extension of time, is enclosed. Also enclosed is a check in the amount of $120.00, the fee for four additional claims (two independent claims and two dependent claims). No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

Applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited. The Examiner is invited and encouraged to contact the undersigned attorney of record at telephone number listed below, if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted.

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